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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/374,142	08/11/1999	HENRY C. LIN	P07-42146	3370

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EXAMINER
NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/374,142	Lin et al
Examiner	**Art Unit**
Mark Navarro	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *12-30 and 56-66* is/are pending in the application.

4a) Of the above, claim(s) *13-20 and 27-30* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *12, 21-23, 26, and 56* is/are rejected.

7) ☒ Claim(s) *24, 25, and 57-66* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's response filed October 15, 2002 (Paper Number 17) has been received and entered.

Claims 12-30 and 56-66 are pending in the instant application, of which claims 13-20 and 27-30 have been withdrawn from further consideration as being drawn to a non-elected species. (See response filed April 30, 2001, Paper Number 6).

Consequently, claims 12, 21-26, and 56-66 are under consideration.

All grounds of rejection in the Office Action mailed June 6, 2002 are withdrawn.

The following new grounds of rejection are applied to the claims:

Claim Rejections - 35 USC § 112

1. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the use of the phrase "derivative." Since it is unclear how the bile acids are undergoing any kind of chemical modification as implied by the recitation of

"derivative." Since it is unclear how the bile acids are to be derived as referred to in the claims, there is no way for the person of skill in the art to ascribe a discrete and identifiable definition to said phrase.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 12 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Rutgeerts et al.

The claims are directed to a method of treating irritable bowel syndrome or Crohn's disease comprising detecting the presence of small intestinal bacterial overgrowth in a human subject having at least one symptom with a suspected diagnosis of irritable bowel syndrome or Crohn's disease, and at least partially eradicating the bacterial overgrowth, whereby the symptom(s) is improved.

Rutgeerts et al (Gastroenterology Vol. 76, No. 5, Part 2, p 1232, 1979) disclose of detecting small intestinal bacterial overgrowth in patients with Crohn's disease. Rutgeerts et al further disclose of the administration of antibiotics to these patients.

In view that Rutgeerts et al disclose of detecting bacterial overgrowth in patients with Crohn's disease and subsequently administering antibiotics which will inherently partially eradicate the bacterial overgrowth, the disclosure of Rutgeerts et al is deemed to anticipate the claimed invention.

It is further noted that patients with Crohn's disease exhibit rebound tenderness and thus are deemed to have the symptom of hyperalgesia.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 12, 21-23 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rutgeerts et al in view of Wellmann et al and Friedman.

The claims are directed to a method of treating irritable bowel syndrome or Crohn's disease comprising detecting the presence of small intestinal bacterial overgrowth in a human subject having at least one symptom with a suspected diagnosis of irritable bowel syndrome or Crohn's disease, and at least partially eradicating the bacterial overgrowth, whereby the symptom(s) is improved; wherein an intestinal lavage or enema is used to partially eradicate the bacterial overgrowth or modifying the subjects diet.

The teachings of Rutgeerts et al are set forth above.

Rutgeerts et al do not teach of an intestinal lavage or enema to partially eradicate the bacterial overgrowth or modifying the subjects diet.

Wellmann et al (Kilin Wochenschr Vol. 60, No. 7, pp 371-374, 1982) teach of reduced hospitalization time for patients with Crohns disease who received intestinal lavages. (See abstract).

Friedman (Gastroenterology Clinics of North America Vol. 20, No. 2, pp 313-324, 1991) teach that elimination of beans, cabbage, lentils, brussel sprouts, and legumes from the diet may reduce the symptoms of irritable bowel syndrome. (See abstract).

Given that 1) Rutgeerts et al have taught of detecting small intestinal bacterial overgrowth in patients with Crohn's disease and further teach of the administration of antibiotics to these patients, and that 2) Wellmann et al have taught that intestinal lavages reduce the duration of Crohns disease, and that 3) Friedman have taught that the elimination of certain foods from the diet reduces the symptoms of Crohns disease, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have incorporated the intestinal lavages as taught by Wellmann et al or the altered diet as taught by Friedman with the method of treating Chrohns disease as taught by Rutgeerts et al. One would have been motivated to combine the teachings based upon the demonstration of the reduction of symptoms of Crohn's disease as taught by both Wellmann et al and Friedman.

Claims 24-25, and 57-66 are objected to as depending upon a rejected base claim, however claims 24-25 and 57-66 are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should by faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

Primary Examiner

November 12, 2002